DOCKET NO.: BTG0008-100 (142769US01) **PATENT**

REMARKS

Claims 60-111 were pending in the present application. Claims 102-122, 124-127, 132-135, 139-142, and 152-163 have been withdrawn from consideration. Claims 115, 128, 129, 136, 143, 144, and 151 have been amended herein. No new matter has been added. Upon entry of the present amendment, claims 112-163 will remain pending.

Applicants thank the Examiner for indicating that claims 112-115 and 123 are allowable.

Applicants also thank the Examiner for indicating that all examined claims are allowable over the prior art of record (see page 6).

Claims 136 and 137 are indicated as being objected to as being dependent from non-elected claim 120. Applicants have amended claim 136 herein accordingly. No new matter has been added. Thus, claims 136 and 137 are now in condition for allowance.

I. The Claims Are Clear And Definite

Claims 115[1], 128-131, 138, and 144 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Applicants respectfully request reconsideration and withdrawal of the rejection in view of the amendments to the claims and the comments presented below.

The Office Action asserts that claims 115, 128, and 129 are confusing by reciting "a peptide of 7-50 amino acids" because SEQ ID NO:2 is longer than 7 amino acids. Applicants have amended claims 115, 128, and 129 to recite "a peptide up to 50 amino acids."

The Office Action also asserts that recitation of "wherein" in claim 129 in "line 118" appears to be surplusage. Applicants respectfully request the Examiner to more particularly point out which recitation of "wherein" in claim 129 appears to be in excess -- Applicants cannot locate "line 118."

[1] Claim 15 has been indicated as being allowed but nevertheless will be addressed herein.

The Office Action also asserts that claim 129 is confusing as to whether a "composition" or "product" is being claimed. Claim 129 has been amended to replace "product" with "composition," which is supported by proper antecedent basis.

Recitation of "the antibody-IFN-γ complex" is alleged to lack antecedent basis in claim 138. Claim 137, however, recites the "kit of claim 136 wherein the means to detect recognition [of the peptide by the T cell] comprises an antibody to IFN-γ." Thus, it is quite clear that when the antibody to IFN-γ comes into contact with IFN-γ, an "antibody-IFN-γ complex" is formed. The formed complex is necessarily an inherent feature and result of carrying out claim 137. Thus, the phrase "the antibody-IFN-γ complex" recited in claim 138 has proper antecedent basis in claim 137.

The Office Action asserts that claim 144 is confusing because the peptide is administered to the skin and there is no obtaining of a "sample" to be used in step a) of claim 143 and no "determining *in vitro*" as in step b) of claim 143. Although claims 143 and 144 are clear as originally written, solely in an effort to advance prosecution, claim 143 has been amended herein. Support for the amendments can be found in the remaining dependent claims wherein it is quite clear that the animal or a sample therefrom can be contacted with the protein and the determination of whether a T cell in the sample recognizes the peptide can be carried out *in vitro* or *in vivo*.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

II. The Claimed Invention Is Supported by Ample Written Description

Claims 116-119, 128-131, and 143-151 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse the rejection and respectfully request reconsideration because the specification provides ample written description supporting the claimed inventions.

The Office Action asserts that recitation of "and other/gliadin/non-gliadin sequence" or derivatives thereof in claims 116-118 is new matter unless the claims are limited to fusion proteins since there is no written description for conjugates. Claims 116-118 are written broadly to encompass all peptides regardless of whether they are fusion proteins or conjugates. Applicants' specification teaches that the agents can comprise SEQ ID NO:1 and other gliadin and non-gliadin sequence (see, for example, page 10, lines 15-17 and page 11, lines 24-31 of the published international application). That Applicants' specification may or may not explicitly recite "conjugates" has no bearing on whether claims directed broadly to SEQ ID NO:1 and "other gliadin or non-gliadin sequence" has sufficient description in the specification. The requirements of §112, first paragraph, however, are met so long as: **(1) the invention is described in the specification as broadly as it is claimed**; and (2) the information provided in the specification is sufficient for persons of ordinary skill in the art having the specification before them to make and use the invention. *In re Marzocchi*, 169 U.S.P.Q. 367 (C.C.P.A. 1971). The specification provides sufficient written description of SEQ ID NO:1 and other gliadin or non-gliadin sequence. Thus, Applicants were clearly in possession of that which is recited in claims 116-118.

The Office Action also asserts that there is no written description for fusion of SEQ ID NO:1 to another gliadin sequence as recited in claims 116, 117, 128, and 129. Applicants teach at, for example, page 11, lines 24-31 of the published international application that the agent can be a product that comprises at least two agents, one of which can be SEQ ID NO:1. Applicants also teach that the other agent can be selected from all of the gliadins present in any of the species or variety mentioned in the application. Applicants also teach at, for example, page 23, line 27 to page 24, line 5 of the published international application, polynucleotides which is capable of expression to provide the agent or mutant gliadin proteins. Applicants further teach that the polynucleotide therefore comprises sequences which encode SEQ ID NO:1, for example, "or any of the agents mentioned herein." Thus, when taken together, Applicants teach a polynucleotide that is capable of expressing a product that comprises at least two agents, one of which is SEQ ID NO:1 and the other of which is any other gliadin. Such an expression product is a fusion protein.

The Office Action asserts that claims 143-151 are not supported by sufficient written description regarding the term "animal." Although the specification amply supports the term "animal", Applicants have amended the claims to recite "individual" which the Office Action indicates is presently supported.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly failing to provide sufficient written description be withdrawn.

III. The Claimed Invention Is Sufficiently Enabled

Claims 116, 117, and 128-131 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office Action mistakenly asserts that it would require undue experimentation for one skilled in the art to use the protein wherein SEQ ID NO:1 or SEQ ID NO:2 is fused to another gliadin sequence and that one skilled in the art would not know whether to use such a protein in diagnostic testing, as an immunization agent, or as a tolerizing agent. Applicants traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

As stated above, Applicants' specification provides ample description of SEQ ID NO:1 or SEQ ID NO:2 fused to another gliadin sequence. The abstract set forth on the cover page of the international application provides one use as a diagnostic for such an agent. For example, the abstract teaches that a method of diagnosing celiac disease by contacting a sample from the host with an agent. The agent can be SEQ ID NO:1, SEQ ID NO:2, or an equivalent sequence from a naturally occurring homolog of the gliadin having SEQ ID NO:3 (see part i). The agent can also be a product comprising two or more agents such as SEQ ID NO:1, SEQ ID NO:2, or an equivalent sequence from a naturally occurring homolog of the gliadin having SEQ ID NO:3 (see part iv). Thus, the specification teaches one skilled in the art to use a protein wherein SEQ ID NO:1 or SEQ ID NO:2 is fused to another gliadin sequence as, for example, a diagnostic.

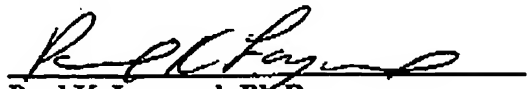
Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation to make and use the claimed invention.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

IV. Conclusion

The pending claims are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative at (215) 665-6914 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,



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